

REMARKS/ARGUMENTS

This Preliminary Amendment is in response to the Examiner's Final Office Action mailed March 28, 2006. Applicants respectfully request reconsideration of the above-referenced application in view of the above amendments and the following remarks.

Information Disclosure Statement

Applicants note with appreciation the Examiner's reviewing of the IDS filed on February 2, 2006. Applicants note that the Examiner did not consider nine of the references for lack of English translation. Applicants further note that the Examiner did not initial Reference IV on page 8.

Applicants attach herewith a Supplemental IDS which include the English equivalent of the nine references not considered previously and the one reference which the Examiner did not mark. Consideration of these references is respectfully requested.

Rejections Under 35 USC 102(b)

Applicants note with appreciation that the Examiner withdrew the rejections of claims 10, 16-17, 20-21, 22-23, 24-25 and 27-28 under 35 USC 102(b) in view of Applicants' amendment filed on March 8, 2006.

Rejections Under 35 USC 112, First and Second Paragraph

The Examiner has maintained the rejection of claims 10, 38, and 49-65 under 35 USC 112, First Paragraph on the grounds that the claims fail to satisfy the written description requirement with respect to leader group L. Similarly, the Examiner has maintained the rejection of the claims under 35 USC 112, Second Paragraph with respect to the leader group L. Because of the close relationship of these rejections, Applicants address the Examiner's rejections together.

Independent Claim 10

Prior to the current amendment to claim 10, the claim specified "a substituted or unsubstituted chain of 3-12 atoms connecting the M substituent to the carbon atom alpha to the L substituent." The Examiner's rejection is based on the assertion that one of ordinary skill in the

art would not know which atoms should be counted in order to determine the separation between the carbon ring alpha to the leader group and the M substituent. On that basis, the claim was rejected for lack of written description under 35 USC 112, First Paragraph and for indefiniteness under 35 USC 112, Second Paragraph.

Applicants amend independent claim 10 as to L to specify that “L is a leader group moiety separating the M substituent from the carbon ring atom alpha to L, wherein the number of **backbone atoms** of the leader group moiety separating the M substituent from the carbon ring atom alpha to L is between 3 and 12.”

Applicants submit that one of ordinary skill in the art would fully appreciate that the backbone atoms of L are the atoms that form the most direct chain of atoms and bonds (i.e., the fewest atoms and bonds) between the M substituent and the carbon ring atom alpha to L. In this regard, the Specification clearly states that the essential function of the leader group is to provide separation between M and the remainder of the inhibitor. Specifically, the backbone atoms serve to extend M “a sufficient distance away from the remainder of the inhibitor so as to allow [M] to interact with the zinc ion while the remainder of the inhibitor interacts with hydrophobic regions in the binding pocket of the histone deacetylase.” Specification, paragraph [00117]. One of ordinary skill in the art will understand that the backbone atoms provide this separation, not the substituents off such backbone atoms. Given this clearly stated function, the Specification teaches that L “may be any substituent comprising a chain of 3-12 atoms connecting the M substituent to the carbon atom alpha to the L substituent.” Specification, Paragraph [00117].

Applicants teach multiple variations of leader groups that fall within the scope of the present invention. For example, Applicants teach that the number of backbone atoms of the leader group moiety separating the M substituent from the carbon ring atom alpha to L may be between 3 and 12 (Paragraph [00121]; claim 10); 3 and 9 (Paragraph [00121]; claim 49); and 4 and 8 (Paragraph [00121]; claim 50).

Applicants also teach that the portion of L that attaches the leader group to the carbon ring atom may include the specific embodiments shown in Figure 2B (claim 38).

Applicants also teach specific embodiments for rings that may form portions of L. These embodiments are shown in Figure 2(c), sheets 1-3 (claims 54-56).

Applicants also teach that one or more of the backbone atoms may include substituents that form rings where the one or more of the backbone atoms form a portion of those rings (Paragraphs [00126] – [00132]; claims 57-66).

Applicants also teach that a portion of the backbone atoms of L form a member of the group shown in Paragraph [00125] (claim 67).

With the teaching that generally, L “may be any substituent comprising a chain of 3-12 atoms connecting the M substituent to the carbon atom alpha to the L substituent” (Paragraph [00117]) and with the extensive teaching at Paragraphs [00118] – [00136] regarding what moieties L may comprise, as well as the synthetic examples that are provided in the Example section, Applicants submit that the definition of L has been provided in the Specification with “reasonable clarity, deliberateness and precision” under the circumstances to show that Applicants were “in possession” of the claimed invention in satisfaction of 35 USC 112, First Paragraph. Specifically, Applicants were “in possession” of the fact that L could be a wide range of moieties with varying substituents so long as “the number of **backbone atoms** of the leader group moiety separating the M substituent from the carbon ring atom alpha to L is between 3 and 12.”

Applicants further submit that the metes and bounds of claim 10 in regard to L, as amended, is definite in that one of ordinary skill in the art will fully understand the intended scope of the claim 10. Specifically, one of ordinary skill in the art can readily identify and count the backbone atoms of L, i.e., the atoms that form the most direct chain of atoms and bonds (e.g., the fewest atoms and bonds) between the M substituent and the carbon ring atom alpha to L.

Withdrawal of the pending rejections under 35 USC 112, First Paragraph and 35 USC 112, Second Paragraph in regard to claim 10 is therefore respectfully requested.

Dependent Claims 38, 49-50 and 54-67

Applicants further submit that dependent claims 38, 49-50 and 54-67, as amended, satisfy both 35 USC 112, First Paragraph and 35 USC 112, Second Paragraph and therefore respectfully request that the Examiner’s rejection as to these dependent claims also be withdrawn.

Rejection Under 35 USC 112, Second Paragraph – Rejection based on “R”

The Examiner rejects claim 56 under 35 USC 112, Second Paragraph on the grounds that the “R” substituent on a number of the five-membered heterocyclic compounds in the claim are undefined. Applicants assume that the Examiner intended to reject claim 55.

Applicants amend claim 55 to remove “R” from the exemplified compounds and respectfully request that the Examiner withdraw the pending rejection of claim 55 under 35 USC 112, Second Paragraph in view of the present amendment to the claim.

Claim Objections

(1) Claim 56

The Examiner objects to new claim 56 under 35 U.S.C. §132(a) on the grounds that the “R” substituent on a number of the five-membered heterocyclic compounds in the claim are undefined. Applicants assume that the Examiner intended to reject claim 55.

Applicants traverse the Examiner’s assertion that these structures are not in the original disclosure. Applicants draw the Examiner’s attention to Figure 2C on Drawing Sheet 7 where the structures are disclosed; thus recitation of these structures in claim 55 does not add new matter.

Applicants amend claim 55 to remove “R” from the exemplified compounds and respectfully request that the Examiner withdraw the pending objection to claim 55 under 35 U.S.C. §132(a) in view of the present amendment to the claim.

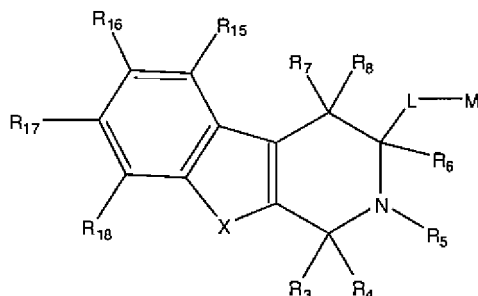
(2) Claims 10 and 36-65

The Examiner objects to claims 10 and 36-65 as containing non-elected subject matter.

Applicants traverse this objection and submit that all pending claims fall within the scope of the elected group.

In the May 31, 2005 Restriction Requirement issued by the Examiner, Group II was defined as:

Claims 1-8, in part, & 10, drawn to the products depicted in Claim 10,



Formula of claim 10

, wherein R1 and R2 of Claim 1 together form indole, benzofuran, or benzothiophene, classified in various subclasses of class 546.

Applicants elected Group II in their August 31, 2005 response to the Restriction Requirement.

Claim 10 recites that X is selected from the group consisting of O, S, and NR₁₄, which thus limits the scope of claim 10 to compounds where R₁ and R₂ of the formula of claim 1 form an indole, benzofuran, or benzothiophene. Accordingly, claim 10 falls wholly within the scope of elected Group II. All other pending claims depend from claim 10. Therefore, all the other pending claims likewise fall within the scope of elected Group II.

Given that all claims fall within the elected group, the Examiner is respectfully requested to withdraw this ground of objection.

(3) Claims 36-65

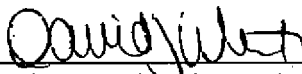
The Examiner objects to claims 36-65 as being dependent upon a rejected base claim. As discussed above, Applicants believe that claim 10, as amended, overcomes the Examiner's rejections. Accordingly, Applicants respectfully request withdrawal of this objection with the withdrawal of the rejections of independent claim 10.

CONCLUSION

Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,
Takeda San Diego, Inc.

Dated: August 25, 2006

By: 
David J. Weitz, General Counsel
& V. P. of Intellectual Property
Reg. No. 38,362

Customer No. 32793
Takeda San Diego, Inc.
10410 Science Center Drive
San Diego, CA 92121
Telephone: (858) 622-8528
Facsimile: (858) 550-0992